

REMARKS/ARGUMENTS

Claims 1-5 and 7-19 are pending

The Action rejects the claims in view of the previously cited Koike reference and newly cited US 5,466,464 to Masaki. The Examiner acknowledges that Koike does not describe the ratio of mannitol to other saccharides and thus relies on the Masaki patent to fill in the deficiency. Specifically, the Examiner finds that Masaki describes a Tablet preparation that includes different blending ratios of mannitol to, for example, lactose in Table 6 (see column 12) which have different disintegration values as shown in Table 1 (see column 9). Therefore, the Examiner argues that it would have been obvious to optimize the ratio of these components to achieve the desired effect, i.e., disintegration time.

Applicants respectfully disagree. First and of significance is Masaki's statement that "A structural body having desired hardness and disintegration rate (dissolution rate) can be obtained **regardless** of their mixing ratio." See col. 3, lines 43-45. This discussion would have clearly indicated to one skilled in the art that the ratios are not important and certainly have no basis to modify the ratios to achieve any effect given Masaki's clear teachings that those ratios are of little importance. Further, many of the blending ratios identified in Table 6 of Masaki fall outside of the scope of the claims and provide nothing with respect to having an excellent balance of both improved oral disintegration times and tableting properties as shown by the evidence presented in this case.

Assuming that sufficient motivation and guidance is considered to have been provided by the cited references to arrive at the claimed weight ratio of mannitol to other saccharide(s) of (98-75) : (2-25), which is clearly not the case, such is rebutted by a showing of superior properties as discussed at length in the previous response.

Briefly and again, as discussed in the present specification and shown by the comparative experimental data presented in the present specification and Table A of the 37 C.F.R. § 1.132 Declaration previously submitted, Applicants have discovered that the tablet compositions of Examples B, 9 and C, which comprise mannitol and other saccharide(s) in the claimed weight ratio of (98-75) : (2-25) in accordance with an exemplary aspect of the present invention, exhibit superior properties with respect to an excellent balance of both improved oral disintegration times and tableting properties, as compared to the inferior properties exhibited by the tablet compositions of Comparative Examples A and D, which comprise mannitol and other saccharide(s) outside the claimed weight ratio of (98-75) : (2-25) (See e.g., page 3, lines 20-25, page 4, lines 1-6, page 6, lines 4-9, page 9, lines 17-21, page 10, lines 3-6, page 30, Example 9).

The evidence clearly demonstrates that the tablet compositions of Examples B, 9 and C, which comprise mannitol and other saccharide(s) in the claimed weight ratio of (98-75) : (2-25) in accordance with an exemplary aspect of the present invention, exhibit superior properties with respect to an excellent balance of both improved oral disintegration times and tableting properties, as compared to the inferior tableting property exhibited by the tablet composition of Comparative Example A, which has a weight ratio of mannitol and other saccharide(s) of (100) : (0), and the inferior oral disintegration time property exhibited by the tablet composition of Comparative Example D, which has a weight ratio of mannitol and other saccharide(s) of (65) : (3), which is similar to the weight ratio described in Koike.

The cited references when considered alone or in combination, fail to disclose or suggest a composition comprising mannitol and other saccharide(s) in a weight ratio of (98-75) : (2-25), as presently claimed. Accordingly, the cited references necessarily fail to recognize that superior properties with respect to an excellent balance of both improved oral disintegration times and tableting properties are exhibited when a composition comprises mannitol and other saccharide(s)

in the claimed weight ratio of (98-75) : (2-25) in accordance with an exemplary aspect of the present invention.

Applicants acknowledge the Examiner's comments on pages 3-4 of the Official Action that in addition to the variations in ratios there was a difference in tableting pressure as so indicated in Table A of the Declaration. This is a non-issue. The tableting pressure varies so that the tablets that are obtained have the same tablet hardness of 3.5 kg. Generally, the disintegration property is measured for tablets having the same hardness. To avoid any effects on disintegration due to the hardness, i.e., so the disintegration can be directly correlative based on composition, the comparative experiments used the same tablet hardness and to achieve this, the tableting pressure varied.

Withdrawal of these grounds of rejection is respectfully requested.

To the provisional obviousness-type double patenting rejections of claims 1-13 and 16-19 over claims 1, 3-28 and 30-32 of copending application 10/945,049 (Tanaka '240, U.S. 2005/0106240, in accordance with MPEP 822.01, it may be appropriate if the "provisional" double patenting rejection is the only rejection remaining, the examiner can withdraw the rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application into a double patenting rejection at the time the present application issues as a patent.

Applicants submit that the present application is now in condition for allowance and notification to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Daniel J. Pereira
Attorney of Record
Registration No. 45,518

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 06/04)